

2009 discharge: European Medicines Agency (EMA)

2010/2173(DEC) - 25/10/2011 - Text adopted by Parliament, single reading

Following the postponement of the discharge decision in May 2011, the European Parliament adopted a decision on **granting the Executive Director of the European Medicines Agency discharge in respect of the implementation of the Agency's budget for the financial year 2009**. The decision to grant the discharge shall also constitute the closure of the accounts for this Agency.

Furthermore, Parliament adopted a resolution with observations which are an integral part of the decision to grant discharge. These may be summarised as follows:

General assessment: Parliament acknowledges receipt of a letter of the Chair of the Agency's Management Board of 17 June 2011 in which it is stated that the **Agency has taken actions to address the 2009 shortcomings**. It regrets, however, that not all the information requested was submitted and call on the Agency should continue to inform on a three-monthly basis the discharge authority on the results of the actions requested by the discharge authority.

Parliament underlines that the discharge authority shall continue to carefully monitor during the upcoming discharge procedures the level of implementation of the measures undertaken to address the Agency's serious weaknesses disclosed by the reports from both the Court of Auditors and the IAS. It expects, therefore, the Agency to inform the discharge authority on the actions implemented and their results and to submit the documents requested, especially with regard to the following issues:

- the process of the adoption by the Management Board of the action plan with specific measures and a timetable for implementation to remedy the shortcomings in the procurement procedures;
- the thorough verification of the effective use of the existing procedures regarding the identification and management of **conflicts of interest** for its staff and experts;
- the submission of the IAS reports according to the Financial Regulation.

Specific observations: Parliament also makes a series of more technical observations in the following areas:

- improving the procurement procedure;
- strengthen technical elements to avoid carry-overs;
- commitment of the Agency to limit risks due to exchange rate variance.

Management of conflicts of interest: overall, Parliament takes note of the Agency's replies on the compliance with its Code of Conduct by setting out principles and guidance on independence and confidentiality applicable to the Management Board and members of committees, experts and the Agency's staff. It acknowledges the Agency's reply in which it is stated that **there is no onus on it to request or monitor the annual declaration of financial interests of experts responsible for evaluating medicinal products, as this lies with the Member States' competent authorities** (Article 126b of Directive 2001/83/EC as amended by Directive 2004/27/EC).

Parliament calls therefore on the Commission to remind the respective authorities in the Member States of their obligations in this matter.

It stresses that it is not only the Agency's reputation that could be affected in cases where evaluations can be challenged on the grounds of possible conflicts of interest but also that such conflicts of interest do not guarantee the optimal protection of European citizens' health. It recalls that there is also an electronic Declaration of Interests (e-DoI) that all experts were requested to fill.

The resolution calls on the Agency to inform the discharge authority on actions taken on issues relating to the effective compliance with its Code of Conduct as regards the management of conflicts of interest. It insists, but also warns the Agency, that all the actions mentioned in the respective audit reports, including the one for the year 2010, should be fully implemented before the start of the next discharge procedure.